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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,143	12/29/2003	W. James Jackson	069748-0304	3867

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,143	JACKSON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 38-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 14-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *070904*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 8/18/06 and 2/29/03.

Election

2) Acknowledgment is made of Applicants' election filed 08/18/06 in response to the restriction and species election requirement mailed 07/24/06. Applicants have elected, with traverse, invention II, claims 5, 6, 8 and 9, and Type B *Neisseria meningitidis* species. Applicants' traversal is on the ground that the Office has not established a serious burden for examining claim 1-51 together. However, Applicants have not advanced any specific arguments in this regard. Applicants have also amended the claim by deleting SEQ ID NO: 2 and SEQ ID NO: 12 from the claims. It is noted that Applicants have elected claims that include SEQ ID NO: 11. The restriction requirement set forth for claims drawn to a polypeptide, a DNA, an antibody, antagonist, a plasmid, and a method of using one or more of the same, is proper for the detailed reasons set forth in the restriction requirement mailed 07/24/06. A search burden is clearly established therein. Therefore, the restriction and species election requirement set forth therein is maintained and is hereby made FINAL.

Status of Claims

3) Claims 5 and 6 have been amended via the amendment filed 04/11/06.

Claims 1-51 are pending.

Claims 10-13 and 38-51 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-9 and 14-37 are under examination.

Information Disclosure Statement

4) Acknowledgment is made of Applicants' information disclosure statement filed 07/09/04. The information referred to therein has been considered and a signed copy of the same is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of Applicants' sequence listing which has been entered on 6/07/04.

Priority

6) The instant application is a divisional of application 09/388,089, filed 08/31/1999, *now US patent 6,693,186*, and claims priority to the provisional application 60/098,685, filed 09/01/1998.

Specification

7) The instant specification is objected to for the following reason:

(a) The amendment made to the first paragraph of the instant specification via the amendment filed 12/29/03 does not accurately reflect the issued status of the parent application as indicated above in italicized letters under 'Priority'. Correction is requested.

(b) The drawings for Figure 2 appear to have two panels, A and B. Under the 'Brief Description of the Figures' at line 26 on page 9 of the specification, the recitation 'Figure 2' should be replaced with --Figures 2A and 2B--. All references to these Figures in the specification should be amended to reflect this change in numbering.

(c) The use of the trademark in the instant specification has been noted in this application. For example, see pages 42 and 49 for 'Tween-20'; see page 48 for 'Eppendorf'; see page 49 for 'Sephacel'; see page 50 for 'Sepharose' and 'Centricon'; and see page 46 for 'Vitale X'. The recitation should be capitalized wherever it appears. See M.P.E.P 608.01(V) and Appendix l. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

Rejection(s) under 35 U.S.C. § 101

8) 35 U.S.C. § 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

9) Claims 7-9 and those dependent therefrom are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claims 7-9, as written, do not sufficiently distinguish over a peptide fragment as it exists naturally, for example on a meningococcal bacterium, because the claims do not particularly point out

any non-naturally occurring differences between the claimed product and the naturally occurring bacterial product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of --isolated peptide fragment-- or --purified peptide fragment-- if descriptive support for such a limitation exists in the instant specification. See MPEP 2105.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

10) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

11) Claims 1-9 and 14-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and indefinite in the use of the abbreviations in the claim language: 'NMASP' and 'SDS'. It is unclear what do these abbreviations stand for. It is suggested that Applicants recite the full terminology at first occurrence in the base claim with the abbreviated terms retained within the parentheses.

(b) Claim 1 is vague and indefinite in the limitation 'about 40' and 'about 55', because it is unclear what is encompassed in the limitation 'about'. Does the limitation 'about' include $\pm$ 5, $\pm$ 10, or $\pm$ 20?

(c) Analogous rejection and criticism apply to claim 2 with regard to the limitation: 'about 44' in claim 2.

(d) Claim 3 is vague, indefinite and/or incorrect in the limitation: '*Neisseria meningitidis* ..... Types A-L and W', because it is unclear what is encompassed in the limitation 'Types A-L and W'. Do the 'Types' represent serotypes, immunotypes, subtypes, or serogroups?

(e) Analogous rejection and criticism apply to claim 4 with regard to the limitation: 'Type A, Type B, Type C or Type W'.

(f) Claim 5 is vague and indefinite in the recitation: 'substantially homologous thereto', because it is unclear what is encompassed in this limitation. What constitutes a 'sequence

substantially homologous thereto' and how much of the amino acid sequence of SEQ ID NO: 11's original structure has to be retained such that the resulting sequence can be considered a 'sequence substantially homologous sequence thereto' is not clear. The metes and bounds of the structure encompassed in the limitation 'sequence substantially homologous thereto' are indeterminate.

(g) Claim 5 is vague and indefinite in reciting 'a sequence .... of SEQ ID NO: 11' without particularly pointing out that SEQ ID NO: 11 is --the amino acid sequence ..... of SEQ ID NO: 11--. In order to distinctly claim the subject matter, in line 3 of claim 5, it is suggested that Applicants replace the limitation 'a sequence' with --the amino acid sequence--.

(h) Claim 6 is vague and indefinite in reciting 'the sequence .... of SEQ ID NO: 11' without particularly pointing out that SEQ ID NO: 11 is --the amino acid sequence ..... of SEQ ID NO: 11--. In order to distinctly claim the subject matter, in line 3 of claim 6, it is suggested that Applicants replace the limitation 'the sequence' with --the amino acid sequence--.

(i) Claim 8 is vague, indefinite and confusing in the limitation: 'A peptide fragment of the NMASP polypeptide of claim 5'. Claim 8 depends from claim 5, which already recites 'a fragment thereof'. Is the 'A peptide fragment of the NMASP polypeptide of claim 5' claimed in claim 8 different from the 'fragment thereof' recited in line 3 of claim 5, or does it encompass the 'fragment thereof' recited in line 3 of claim 5?

(j) Claim 9 is vague, indefinite and confusing in the limitation: 'A peptide fragment of the NMASP polypeptide of claim 6'. Claim 9 depends from claim 6, which already recites 'a peptide fragment thereof'. Is the 'A peptide fragment of the NMASP polypeptide of claim 6' claimed in claim 9 different from the 'peptide fragment thereof' recited in line 1 of claim 6, or does it encompass the 'peptide fragment thereof' recited in line 1 of claim 6?

(k) Claim 4 is vague, indefinite, and incorrect in the limitation: 'The NMASP polypeptide of claim 3, which *Neisseria meningitidis* is Type A, Type B, Type C or Type W'. Is the NMASP 'polypeptide' a *Neisseria meningitidis* of Type A, Type B, Type C or Type W? The phrase does not make sense.

(l) Claim 19 is vague, indefinite, and has improper antecedence in the limitation: 'the lipid'. Claim 19 depends from claim 18, which recites 'lipids', but not 'a lipid'.

(m) Claim 21 is vague, indefinite, and has improper antecedence in the limitation: 'the

lipid'. Claim 21 depends from claim 20, which recites 'lipids', but not 'a lipid'.

(n) Claim 27 is vague, indefinite, and has improper antecedence in the limitation: 'the lipid'. Claim 27 depends from claim 26, which recites 'lipids', but not 'a lipid'.

(o) Claim 29 is vague, indefinite, and has improper antecedence in the limitation: 'the lipid'. Claim 29 depends from claim 28, which recites 'lipids', but not 'a lipid'.

(p) Claim 35 is vague, indefinite, and has improper antecedence in the limitation: 'the lipid'. Claim 35 depends from claim 34, which recites 'lipids', but not 'a lipid'.

(q) Claim 37 is vague, indefinite, and has improper antecedence in the limitation: 'the lipid'. Claim 37 depends from claim 36, which recites 'lipids', but not 'a lipid'.

(r) Claims 2-9 and 14-37, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

12) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13) Claims 1-4, 14, 16, 18, 19, 22, 24, 26, 27, 30, 32, 34 and 35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brodeur *et al.* (*Infect. Immun.* 50: 510-516, 1985) as evidenced by Rodriquez *et al.* (US 5,286,484).

The transitional limitations 'having', 'comprising', 'including', 'containing', or 'characterized by', represent open-ended claim language and therefore, do not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). Therefore, the limitation 'comprising' or 'contains' in the instant claim(s) allows additional amino acid residues to be present on one or either side of the recited polypeptide, or a fragment or peptide fragment thereof. It should be noted that the transitional phrase 'consisting of' excludes any element, step, or ingredient not

specified in the claim. *In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('consisting of' defined as 'closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.').

Brodeur *et al.* taught an immunizing composition (i.e., antigenic composition or pharmaceutical composition) comprising phosphate-buffered saline (i.e., pharmaceutically acceptable carrier), Freund's complete adjuvant, and 20 micrograms of an outer membrane protein (i.e., polypeptide) preparation isolated from serogroup (i.e. Type) B *Neisseria meningitidis*. The protein has a molecular weight of 43,000 (i.e., about 44 kD) as determined by SDS polyacrylamide gel electrophoresis and reacts with the protein-specific antibody. See pages 511 and 512; 'Results', and Figure 1. Since the prior art outer membrane protein preparation is not a purified preparation, it is expected to contain phospholipids and the meningococcal lipopolysaccharide immunogen at least as a contaminant. For example, Rodriquez *et al.* taught that *Neisseria meningitidis* outer membrane components intrinsically comprise lipopolysaccharides and phospholipids. See fourth full paragraph in column 2 of Rodriquez *et al.* Although Brodeur *et al.* do not refer to their polypeptide as NMASP, the prior art 43 kD *Neisseria meningitidis* protein is viewed as the same as the Applicants' claimed polypeptide. The Office's position that Brodeur's protein is the same as the Applicants' polypeptide is based upon the overlapping molecular weight and the serogroup B *Neisseria meningitidis* bacterial origin of the prior art protein or polypeptide. Therefore, the prior art isolated protein is expected to necessarily have the same intrinsic structure and properties as that of the Applicants' polypeptide.

Claims 1-4, 14, 16, 18, 19, 22, 24, 26, 27, 30, 32, 34 and 35 are anticipated by Brodeur *et al.* The reference of Rodriquez *et al.* is **not** used as a secondary reference in combination with the reference of Brodeur *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Brodeur *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

14) Claims 5-9 and 14-37 are rejected under 35 U.S.C § 102(b) as being anticipated by Quaissi *et al.* (*Science* 234: 603-606, 1986) as evidenced by Qin *et al.* (*J. Immunol.* 150: 2072-2080, 1993) and Haites *et al.* (*J. Biol. Chem.* 280: 10981-10987, 2005).

The transitional limitations 'having', 'comprising', 'including', 'containing', or

'characterized by', represent open-ended claim language and therefore, do not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). Therefore, the limitation 'comprising' or 'contains' in the instant claim(s) allows additional amino acid residues to be present on one or either side of the recited polypeptide, or a fragment or peptide fragment thereof. It should be noted that the transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim. *In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('consisting of' defined as 'closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.').

Quaissi *et al.* taught an isolated, synthetic peptide comprising the RGD sequence. A vaccine composition (i.e., antigenic composition or pharmaceutical composition) comprising saline (i.e., pharmaceutically acceptable carrier), Freund's complete adjuvant, and the peptide conjugated to tetanus toxoid is taught. Quaissi's RGD peptide sequence constitutes a peptide fragment of the instantly recited NMASP comprising the amino acid sequence of SEQ ID NO: 11, being located at amino acid positions 451-453 of SEQ ID NO: 11. Therefore, Quaissi's RGD peptide fragment is expected to specifically bind to an antibody that specifically binds to Applicants' SEQ ID NO: 11. That Freund's complete adjuvant (CFA) contains an immunogen such as, *Mycobacterium* strain H37Ra, and that mycobacteria intrinsically contain abundant phospholipid in their cell membrane, are inherent from the teachings of Quaissi *et al.* in light of what was known in the art. For example, Qin *et al.* taught that CFA contains *Mycobacterium* strain, H37Ra (see second paragraph under 'Materials and Methods' of Qin *et al.*) and Haites *et al.* taught that mycobacteria contain abundant phospholipid in their cell membrane (see abstract of Haites *et al.*).

Claims 5-9 and 14-37 are anticipated by Quaissi *et al.* The reference of Qin *et al.* or Haites *et al.* is **not** used as a secondary reference in combination with the reference of Quaissi *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Quaissi *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Objection(s)

15) Claim 2 is objected to for the incorrect limitation: 'TO' (see line 2). It is suggested that Applicants replace the limitation with the recitation --to--.

Remarks

16) Claims 1-9 and 14-37 stand rejected.

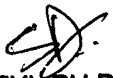
17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Action supervisor, Albert Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



S. DEVI, PH.D.
PRIMARY EXAMINER

October, 2006